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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,670	02/09/2004	Ramez Emile Necola Shehada	064693-0097	1453

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MCDERMOTT, WILL & EMERY
Suite 3400
2049 Century Park East
Los Angeles, CA 90067

EXAMINER

HILL, LAURA C

ART UNIT	PAPER NUMBER
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3761

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04/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO. ^{ED}
10775670	2/9/2004	NECOLA SHEHADA, RAMEZ EMILE	064693-0097

MCDERMOTT, WILL & EMERY
Suite 3400
2049 Century Park East
Los Angeles, CA 90067

EXAMINER

Laura C. Hill

ART UNIT	PAPER
3761	20070425

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Office Action Summary

Application No.

10/775,670

Applicant(s)

NECOLA SHEHADA, RAMEZ
EMILE

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/18/07; 3/19/07; 3/29/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 March 2007 has been entered.

Information Disclosure Statement

The information disclosure statements filed 18 January 2007, 19 March 2007 and 29 March 2007 comply with 37 CFR 1.97 and thus have been considered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20, 25, 30 and 35 are provisionally rejected on the ground of nonstatutory double patenting over claims 68, 74 and 78 of copending Application No. 10/775,666.

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This is a provisional double patenting rejection since the conflicting claims have not yet been officially patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a surgical drain implanted in the body to rest against but not penetrate the surface of an internal tissue; an energy emitting element; an energy receiving element; and a tube.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

Applicant's arguments, see page 1, filed 19 March 2007, with respect to claims 1-19 have been fully considered and are persuasive. The rejection of the claims is rendered moot since they have been cancelled has been withdrawn.

Claim Amendments

Examiner concurs with Applicant's statement that support for new claims 20-35 is found at least in figure 4B and paragraph 66 of the instant specification.

Allowable Subject Matter

Claims 20-35 are allowed.

The following is an examiner's statement of reasons for allowance: the art of record alone or in combination fails to disclose or fairly suggest a surgical drain with a plurality of drain holes configured to rest against the surface of the tissue and to not penetrate the tissue. The following is the closest prior art:

Fonger et al. (US 5,291,896) discloses cardiac output probe assembly 10 with drainage tube 12 having drainage holes 44, output probe/energy emitting element adapted for placement *within/*penetrating the thoracic cavity tissue (column 3, lines 35-53, column 4, lines 29-32 and lines 50-56, figure 1).

Benaron et al. (US 5,769,791) discloses surgical tool 30,210 with tip 40 passing through or around internal body tissue (column 10, lines 29-38) or alternatively resting on tissue 207 and not penetrating through ti (column 18, lines 14-15, figure 6) comprising first transmitting element 22, 241,242 provides a light control signal using optical fibers (column 9, lines 23-31, column 18, lines 15-18), first sensing element 24, 245, 246 that receives signals corresponding to the detected light (column 18, lines 20-21, figure 6), performs a color analysis and ascertains the desired spectral characteristics of the detected light, and provides the spectral data to the signal processor 26 (column 9, lines 32-36) which in turn provides the type of tissue to display system 28 (column 9, lines 38-42). However, Benaron doesn't disclose a surgical drain having a tube to transport drained fluid out of the body or sensor and transmitter embedded within tool or any motivation to modify the device to have a surgical drain.

Crowley (US 6,882,875) discloses an interventional device 10, 90 inserted into the body (column 3, lines 15-16) and positioned against tissue 92 (column 5, lines 1-2,

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figure 5A) comprising a first transmitter 20 on the inner surface of the body (column 3, lines 25-40, figure 1), a sensor or light source 16 or LEDs 38a, 38b for providing a signal (column 3, lines 45-52, column 4, lines 16-20), processor and display 14 (column 3, lines 19-24) but no surgical drain having a tube to transport drained fluid out of the body or sensor and transmitter embedded within tool or motivation to combine with surgical drains since all other surgical drains (e.g. Russo US 4,317,452) penetrate inside the tissue and don't have sensing or transmitting means.

Mayevsky (US 5,916,171) discloses a device that simultaneously monitors NADH, CBF and other physiological properties using a bundle of optical fibers resting against the surface of the tissue (column 4, lines 10-20, column 6, lines 52-53, columns 9-10, table 3) but no surgical drain.

Frank (US 3,769,497) discloses a biomedical device having a surgical drainage tubing 13 coming from a catheterized patient having transmitting switch 19 and sensing device 16 for transmitting and detecting energy (column 2, lines 7-38, figure 1). One would not be motivated to modify the sensing devices of Benaron, Crowley or Mayevsky listed above with the drain since Frank discloses a drain that *penetrates* the tissue. Even if the modification took place, the transmitting and sensing devices 19, 16 respectively are not integrated on the outer surface of the drain but rather are located remotely from the drain 13 (figure 1).

Takezawa et al. (US 5,108,364) discloses catheter 1 that is *implanted into a body cavity* and thus penetrates the tissue (column 3, lines 55-65) having temperature sensor 10 that detects energy and embedded within the catheter (column 4, lines 9-15), processor

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and display (column 4, lines 9-10) and drainage holes 5 (column 3, lines 29-38, figure 1A), and a second sensor that can simultaneously measure temperature at a plurality of regions (column 4, lines 24-26). However, there is no transmitter or colors that are determined or depicted but rather temperature is monitored.

Bedingham (US 5,421,328) discloses an arterial catheter 53 with oxygen sensor 69, carbon dioxide sensor 71, and pH sensor 73 affixed to a distal end of transmitting element/optical fibers 75,77,79 on an inner surface of the catheter (column 7, lines 46-51, column 8, lines 2-4 and figure 2). Thus the catheter is implanted and penetrates the tissue.

Sullivan et al. (US 4,497,324) discloses a urinary , interperitoneal, intercardial, respiratory or intervacular catheter penetrating the tissue (column 5, lines 7-11) having drainage lumen 20 (column 3, lines 31-39), temperature transducer/sensor 32 imbedded in the catheter wall to detect temperature and convert said temperature to an electrical signal (column 3, lines 60-63), and a transmitting element/electrical lead 34 imbedded in the catheter wall (column 4, lines 19-20).

Yanda (US 4,413,633) discloses catheter tube 10 inserted into a urethra and thus penetrating the tissue that forms the urethra and connected to drainage tube 30 (column 2, lines 32-35 and lines 42-47), sensor 38 and transmitter on inner surface of the catheter (column 3, lines 18-39 and figure 2).

Pavoni et al. (US 5,906,584) discloses electrodes/sensors 5 on outer surface of catheter 3 but catheter is inserted within tissue, and a monitor/reading apparatus and a

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power supply/energy delivery transmitting element (column 4, line 36-column 5, line 8, figures 6-7). Also there is no drain disclosed.

Frazee (WO 92/11803) discloses cardiopulmonary monitoring system 100 that transmits and receives optical signals to and from the interior of the penetrated blood vessel via fiber optic catheter 10, monitor/display, and processing (see abstract, etc).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (hours vary).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C Hill
Examiner
Art Unit 3761

LCH



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

